IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Andrulis Pharmaceuticals Corp.,	
Plaintiff,	
v.	Civil Action No. 13-1644 (RGA)
Celgene Corp.,	
Defendant.	

MEMORANDUM OPINION

Kenneth L. Dorsney, Esq., Morris James LLP, Wilmington, DE; Paul J. Skiermont, Esq. (argued), Skiermont & Puckett LLP, Dallas, TX; Sarah Spires, Esq., Skiermont & Puckett LLP, Dallas, TX; Steve Udick, Esq., Skiermont & Puckett LLP, Dallas, TX; Attorneys for Plaintiff

Mary B. Graham, Esq., Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; Calvin P. Griffith, Esq. (argued), Jones Day, Cleveland, OH; John Evans, Esq., Jones Day, Cleveland, OH; Jennifer Swize, Esq., Jones Day, Washington, DC; Attorneys for Defendant

June <u>16</u>, 2015

Ruhand G. and MM2-ANDREWS, U.S. DISTRICT JUDGE:

Plaintiff asserts claim 2 of U.S. Patent No. 6,140,346 (the "'346 Patent") against Defendant. (D.I. 89 at 9). The patent at issue broadly relates to the treatment of cancers using methods and combinations that include thalidomide and other agents. (*See* '346 Patent, Abstract). The specification states that the invention relates to a "novel method for treating cancers with thalidomide alone or in combination with other antiangiogenic and anti-cancer agents." ('346 Patent at 1:8-10). Presently, the parties have requested that the Court construe five terms. The Court has considered the parties' joint claim construction brief (D.I. 89), the parties' claim construction appendix (D.I. 90), and held oral argument on the matter. (D.I. 138).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). ""[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law." *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually,

¹ The briefing contained six disputed terms, but the parties later agreed that the term "in combination with" need not be construed. (D.I. 129).

it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . .

[Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Id. at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." Id. at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314 (internal citations omitted).

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." Renishaw PLC v. Marposs Societa' per

Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." Osram GmbH v. Int'l Trade Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

II. CONSTRUCTION OF DISPUTED TERMS

The asserted claim 2 of the '346 Patent reads:

A method for the treatment of *neoplastic diseases* in a mammal which comprises administering to said afflicted mammal enhanced therapeutically-effective amounts of thalidomide in combination with effective amounts of other alkylating agent selected from the group consisting of mechlorethamine, cyclophosphamide, ifosamide, melphalan, chlorambucil, busulfan, thiotepa, carmustine, lomustin, cisplatin, and carboplatin wherein said neoplastic diseases are sensitive to said enhanced combination.

('346 Patent, Claim 2) (relevant terms italicized).

- 1. "administering"
- a. Plaintiff's proposed construction: Ordinary and customary meaning.

 Alternatively: "to mete out"
 - b. Defendant's proposed construction: delivering into a [mammal's] body
 - c. Court's construction: delivering into or onto a [mammal's] body

Drawing from its expert Dr. Robert M. Williams, Plaintiff argues that a person skilled in the art would understand "administering" within the context of medicine. (D.I. 89 at 17). Plaintiff argues that a lay juror with experience with prescription medicine would also likely understand the term. Plaintiff disagrees with Defendant's more limiting construction because in the context of medicine administering is not limited only to "applying onto or into" a patient, but could also include to give, to mete out, or to supervise the formal taking of. (D.I. 89 at 17-18). Plaintiff also points out that the specification identifies that "therapeutic treatment with

thalidomide can utilize any type of administration," implying that the term cannot be limited only to "applying onto or into" a patient. (D.I. 89 at 17-18; '346 Patent at 10:16-20).

Defendant argues that its construction of "administering" as "deliver into a [mammal's] body" is the ordinary meaning of the term in the context of a claimed treatment targeting a disease. (D.I. 89 at 19). According to Defendant, the "only way to treat diseases in the body using the claimed drugs is to deliver the drugs into the body." (*Id*). Defendant also points to the specification's examples of administrating involving delivery into the body, such as oral, topical, injection, or intravenous administration. (D.I. 89 at 20; '346 Patent at 10:16-20).

Plaintiff responds that it is concerned that Defendant is trying to remove prescribing medication from the meaning of administering. (D.I. 89 at 18). More specifically, Plaintiff argues that Defendant is attempting to direct the claim language at "diseases" rather than "patients." (D. 89 at 24). Defendant responds that Plaintiff is attempting to depart from the ordinary meaning of the term. (D.I. 89 at 27). Defendant argues that "Andrulis does not, and cannot, point to anything in the patent disclosing methods of prescribing, dispensing, or overseeing drugs." (D.I. 89 at 28).

Administering as understood by a person of ordinary skill in the art must be limited to delivering a drug into or onto a mammal. If Plaintiff's proposal of "to mete out" is accepted, the term would be so overly broad as to cover nearly any action associated with dispensing a drug. It would not be appropriate for "administering" in the claim to cover the acts of pharmacists, sales people, or essentially anyone giving or handing the drug to a patient. Instead, administering must be tied to the process of administering the medicine in the context of immediately providing treatment. Administering a drug must mean that it is directly delivered into or onto a patient. Therefore, when the specification states that the treatment "can utilize any

type of administration including oral administration, topical application, intramuscular injection and intravenous infusion," what is noteworthy about all of those examples of administration is that they describe delivering the drug into or onto the body. ('346 Patent at 10:16-19). It is true that the patent describes "any" administration "including" administrations that deliver into or onto the body, suggesting that other types of administrations are not necessarily foreclosed.² But within the context of the patent, Plaintiff does not provide any evidence for a meaning of administration beyond those that deliver the drug into or onto the body for the treatment to occur. Because the specification identifies topical application as a type of administration, administering must mean not only delivering into a patient, but also delivering onto one. Therefore the term "administering," in the context of the patent, must mean "delivering into or onto a [mammal's] body."

- 2. "enhanced" and "enhanced combination"
- a. Plaintiff's proposed construction: "synergistic" and "synergistic combination"
- b. Defendant's proposed construction: Subsumed in "enhanced therapeutically-effective amounts of thalidomide" and/or "said neoplastic diseases are sensitive to said enhanced combination"; indefinite.
 - c. *Court's construction*: indefinite

Plaintiff argues that the term "enhanced" was introduced in the claim language during prosecution in response to an examiner advising that claims concerning drug combinations

² For example, if the treatment could be made into a nasal spray, inhalation would be within the scope of administration.

"directed to a showing of greater than additive effect" would overcome prior art. (D.I. 89 at 30; D.I. 90-1 at 23). Therefore, according to Plaintiff, "enhanced" was used "for the specific purpose of clarifying that the claimed combination shows 'greater than additive effect." (D.I. 89 at 31).

Defendant argues that enhanced is a term that requires degrees, but the patent never defines whether the claimed enhancement is less than additive, additive, or greater than additive. (D.I. 89 at 33). Defendant also challenges Plaintiff's interpretation of the prosecution history. Defendant notes that Plaintiff could have accepted the examiner's language of "greater than additive" but instead used the language "enhanced," suggesting a difference in meaning. (D.I. 89 at 34). The applicant disputed the examiner's reading of the prior art when amending the claim, citing evidence "illustrating the success of thalidomide in combination with anticancer agents," stating that the prior art at question did not demonstrate the success found in that cited evidence. (D.I. 89 at 34; see D.I. 90-1 at 28). According to Defendant, that cited evidence did not demonstrate that the combination was greater than additive, only that the combination was effective.

The term "enhance" in common usage means to "improve," "increase" or "intensify." (D.I. 90-3 at 10). In the medical field, a synergistic effect means an effect of or relating to two or more agents that have a combined effect that is greater than the sum of their individual effects. (See D.I. 90-3 at 6). The Court accepts that "synergistic" is a synonym of "greater than additive."

The central issue is whether enhanced means greater than additive or whether it renders the claim indefinite. The Supreme Court has said that 35 U.S.C. § 112 "require[s] that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art

about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). "The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 2015 WL 3772402, at *5 (Fed. Cir. June 18, 2015).

Absent evidence narrowing the meaning of "enhanced," the Court is persuaded that the term is indefinite because it could mean less than additive, additive, or greater than additive. At oral argument, Defendant conceded that if enhanced is construed to cover all three, the claims would be indefinite. (D.I. 138 at 73-74) ("...your question was if it can be any of those three [less than additive, additive, or greater than additive], would it be indefinite. And I said yes. And the reason I said yes is because there's no way it can mean less than additive effect if you look at the intrinsic record. If the conclusion that you drew from the intrinsic evidence was additive or greater than additive, I would not concede that that is necessarily indefinite."). Neither side has offered any evidence that enhanced means only additive or only less than additive. Therefore, the definiteness of the term turns on whether enhanced means greater than additive. If it does not, it is indefinite.

The patent itself does not provide much guidance on the meaning of enhanced. The term shows up in the specification only twice. In the most helpful example, the patent describes thalidomide given in combination with other agents: "An example of such combination therapy could involve thalidomide given with pentoxifylline and a glucocorticoid such as

³ Unlike "synergistic," it is not apparent that there is a consensus about what "enhanced" as a general term means to a person of ordinary skill in the art. Plaintiff's expert opines that "in light of the specification and prosecution history" a person of ordinary skill would understand it to mean "synergistic." (D.I. 90-1 at 64). In contrast, Defendant's expert opined, "It is my opinion that a person of ordinary skill would interpret the term 'enhanced' to encompass all degrees of enhancement, including less than additive, additive, and synergistic enhancement." (D.I. 90-1 at 155).

dexamethasone. The activity of each of these agents would be expected to enhance that of the other two in inhibiting TNF-alpha synthesis since each of these agents acts as a inhibitor at a different point in this synthesis." ('346 Patent at 8:25-31). Expecting to enhance the other agents does not necessarily mean that the result is greater than additive or greater than the sum of its parts. It is not even self-evident from this usage in the specification that the use of "enhance" is consistent with how it was used in the claim to modify "combination" or "amount of thalidomide."

The prosecution history, when read fully, does not support Plaintiff's position. It is true that the examiner told the applicant during prosecution that claims showing a "greater than the additive effect" would overcome a particular piece of prior art, Liversidge et. al. (D.I. 90-1 at 23) ("Claims directed to a showing of greater than the additive effect would overcome this rejection."). The applicant in response did add "enhanced" to the patent claims, implying that term would overcome the Liversidge prior art—but that does not mean enhanced is the same as "greater than additive." (D.I. 90-1 at 28) ("Applicant has now amended the claims to read an enhanced effective amount ..."). The fact that the applicant used "enhanced" rather than "greater than additive" suggests that the applicant chose not to expressly adopt the examiner's position, as the applicant could have easily used the examiner's suggested language. The applicant did not expressly say what was meant by "enhanced." Based on common usage alone, it would seem that the applicant opted for "enhanced" because it was broader than "greater than additive."

⁴ Or, the applicant could have used some variation of "synergistic," which appears to be the term of art for "greater than additive."

The prosecution history demonstrates that the applicant did not simply adopt the examiner's position that the claims require a greater than additive effect. This point becomes more clear when the next paragraph of the applicant's response is examined, where the applicant "vigorously disagree[d]" with the examiner's reliance on the Liversidge prior art: "Applicants vigorously disagree with the assertion in the Office Action stating that one skilled in the art would reasonably expect to arrive at the compositions and method of the present invention. The Office has failed to show where in Liversidge et al. there is a teaching or suggestion of the use of thalidomide in combination with other anticancer agents." (D.I. 90-1 at 29). If the Liversidge prior art did not teach this combination, then the applicant did not need to overcome the rejection by amending the claims to have a greater than additive effect. Adding "enhanced" might make the claims different, but the new term, at least according to the applicant's position, does not really relate to whether or not the claims now require a greater than additive (or some other) effect. The applicant did not merely adopt the examiner's position on Liversidge but disagreed with it. Therefore, Plaintiff cannot simply state that the applicant used "enhanced" to adopt the examiner's position on "greater than additive." It cannot be the case that "enhanced" is merely a synonym for "greater than additive" when read within the context of the examiner's rejection, and the applicant's amendment and response.

At the oral argument, much was made of an exhibit attached to the applicant's response to the examiner in the prosecution history, which included a USA Today article and a report from New York University School of Medicine. In the briefing, only Defendant really focused on this point. (*See* D.I. 89 at 35). The content of these articles is relevant because after amending the claim to include enhanced, the applicant stated "There is no evidence or recognition in the Liversidge et al. Patent that the combination of thalidomide with other

anticancer agents provide the results outlined in Exhibit A." (D.I. 90-1 at 28). The exhibit, therefore, could illuminate the meaning of the term "enhanced." The first document in the exhibit, a preliminary NYU study, does not clearly show a greater than additive effect; indeed, it appears to be cut off before the "Conclusions" section. (See D.I. 90-1 at 31-35). The second document in the exhibit, a Dow Jones Business News article is a summary of preliminary results related to thalidomide's effectiveness in combination with chemotherapy. (D.I. 90-1 at 36-38). The article is just a wrap up of other research, and it does not identify a greater than additive effect. Indeed, the document does not relate to, or demonstrate, a greater than additive effect. The final document raised by the parties at oral argument is a USA Today article, which mentions research about how thalidomide used in combination with chemotherapy is effective. (D.I. 90-1 at 39-40). Even though the article says that studies suggest that patients with the drug combination live longer, it does not demonstrate a greater than additive effect or some other meaning for enhanced. The materials in Exhibit A, therefore, do not support a reading of enhanced that means greater than additive—or really illuminate the meaning of enhanced in any way.

The parties also rely on testimony of the inventor, but the Court does not find this evidence helpful in construing this term. Defendant's arguments that the inventor, Dr. Murray Drulak, stated "enhanced" could mean "any number of things" is not inconsistent with the general proposition that enhanced, without more context, is indefinite. (D.I. 89 at 33). Dr. Drulak's deposition testimony on that term, however, was not specifically about its meaning when used by the claims in the patent, so the testimony is less persuasive than Defendant represents it to be. (D.I. 90-1 at 250) ("I didn't write the article, so I don't know what his intent was in using – that is a general term, 'enhance.' It could mean a number of things including a

synergistic effect."). The more pertinent testimony on this point is cited by Plaintiff, when the inventor is questioned specifically about the mechanism in the '394 patent:

- Q. Did you believe that the combination of Thalidomide with an alkylating agent would be effective to treat cancer?
- A. Yes.
- Q. Why?
- A. Well that was the basis of the patent. Because alkylating agents have one mechanism of action and Thalidomide has another. So putting them together would get an enhanced effect of the two in treating cancer.
- Q. By "enhanced effect," what do you mean?
- A. A synergistic effect.
- Q. By "synergistic," what do you mean? How do you determine whether something is synergistic?
- Q. Well, the overall effect of the two together would be greater than the additive effect of the two separately.

(D.I. 90-1 at 240).

Dr. Drulak clearly believes that the enhanced effect of the patent refers to a greater than additive effect, as this testimony reveals. It does not matter, however, what he believes. The relevance of the inventor's deposition testimony from January 2015—15 years after the patent was issued—on the meaning of enhanced effect is useless. *See Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008) ("As we have explained, it is not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO. ... We hold that inventor testimony as to the inventor's subjective intent is irrelevant to the issue of claim construction") (internal quotation marks omitted). It is not apparent that Dr. Drulak is describing the meaning of "enhanced" in the claim so much as the mechanism, as he sees it, of the invention. Even then, he uses multiple terms to clarify the meaning of "enhanced effect," such as synergistic effect and greater than additive, implying that the term "enhanced" may not provide enough specificity on its own.

Similarly, the value of the other experts in determining the meaning of the term is limited. Plaintiff spends much time attempting to discredit Defendant's expert, Dr. Ivan M. Borrello, because he did not draft portions, or perhaps all, of his declaration, and he had not seen some materials his declaration relies on. (D.I. 89 at 43). Plaintiff also questions Dr. Borrello's specialty in oncology, and notes that he has never participated in a patent infringement lawsuit. Plaintiff will be able to cross-examine Dr. Borrello at trial on these issues. Since I am not relying upon Dr. Borrello's declaration, I need not consider them.

For the above reasons, "enhanced" cannot be construed to mean synergistic or greater than additive—especially when that language was made available to the patent applicant. A patent's claims when read in light of the specification and prosecution must inform a person skilled in art of the invention with reasonable certainty, else they are indefinite. *Nautilus, Inc.*, 134 S. Ct. at 2129. Because "enhanced" can mean less than additive, additive, or greater than additive, the term is indefinite because it does not inform a person skilled in art of the invention with reasonable certainty of its meaning in the patent-in-suit.

- 3. "enhanced therapeutically-effective amounts of thalidomide"
- a. Plaintiff's proposed construction: incomplete fragment that must be read in context of full phrase ... accordingly, "therapeutically-effective amounts of thalidomide that, in combination with effective amounts of other alkylating agent, have synergistic effect."
 - b. Defendant's proposed construction: indefinite
 - c. Court's construction: indefinite

The parties make similar arguments about the meaning of "enhanced" and whether or not it is indefinite. (D.I. 89 at 51-54). Plaintiff argues that "enhanced" in the phrase at question

modifies a combination of thalidomide and an alkylating agent. (D.I. 89 at 51). Defendant argues that following normal rules of grammar "enhanced" modifies "therapeutically-effective amounts of thalidomide." (D.I. 89 at 52).

For the same reasons mentioned earlier, "enhanced" by itself is indefinite, but here, the grammatical structure adds a second reason for a finding of indefiniteness.

I do not think that "enhanced" modifies "in combination" or "combination" in this phrase, as Plaintiff argues. Under normal rules of grammar, and absent a compelling reason, an adjective modifies a noun close to it, usually following the adjective. See William Strunk Jr., The Elements of Style 30 (2000) ("Modifiers should come, if possible, next to the words they modify."); see also The Chicago Manual of Style 168 (2003) ("An adjective that modifies a noun or noun phrase usually precedes it."). Here, "enhanced" is followed by "therapeutically-effective amount of thalidomide," and "enhanced" should modify the amount of thalidomide, not the "combination." For the reasons mentioned in the earlier claim construction analysis, the claim requires two agents, as Defendant points out: "[1] enhanced therapeutically-effective amounts of thalidomide in combination with [2] effective amounts of other alkylating agent[s]." (See D.I. 89 at 52). Just as "effective" modifies "amount of other alkylating agent[s]," "enhanced" modifies "therapeutically-effective amounts of thalidomide." If the drafters of the claim wished for "enhanced" to modify "combination," they could have easily rewritten the claim to place "enhanced" immediately before "combination." Indeed, that is precisely what the drafters did when they ended claim 2 with the phrase "said enhanced combination," demonstrating that "enhanced" could have easily been placed in front of combination. Plaintiff points to this express language of "said enhanced combination," but it does not prove Plaintiff's point about the earlier "enhanced," which precedes amounts of thalidomide.

Claims 1 and 3 both use a similar phrase that unequivocally demonstrates that "enhanced" was used to modify "amount[s] of thalidomide" and not combination. ('346 Patent, Claimss 1 & 3). For example, claim 1 comprises:

- (a) an enhanced effective amount of thalidomide;
- (b) an effective amount of an alkylating agent selected from the group consisting of mechlorethamine, cyclophosphamide, ifosamide, melphalan, chlorambucil, busulfan, thiotepa, carmustine, lomustin, cisplatin, and carboplatin; and (c) a pharmaceutically acceptable inert carrier.

('346 Patent, Claim 1).

In claim 1's phrase "enhanced effective amount of thalidomide," it is as clear as it can be that "enhanced" modifies "amount of thalidomide" and not "amount of an alkylating agent." In light of claims 1 and 3's use of a similar phrase, it is not reasonable to use grammatical gymnastics to force "enhanced" to modify "combination" when "enhanced" immediately precedes "[therapeutically-effective] amount of thalidomide." The patent claims, in this case, present compelling evidence of how they must be read. This Court must construe the terms as written—even if the claims are poorly drafted. *See, e.g., Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("[I]t is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.").

Because "enhanced" in this phrase must modify "amount of thalidomide," this term must be indefinite because it is unclear what an "enhanced" amount of thalidomide (or an "enhanced" therapeutically-effective amount of thalidomide) would be. For the above reasons, the term is found to be indefinite because it does not inform a person skilled in the art with reasonable certainty of its meaning. *See Nautilus, Inc.*, 134 S. Ct. at 2129

4. "neoplastic diseases"

- a. Plaintiff's proposed construction: Ordinary and customary meaning.

 Alternatively: "cancers"
 - b. *Defendant's proposed construction*: solid tumor cancers
 - c. Court's construction: cancers

Plaintiff argues that the patent's specification confirms an ordinary and customary meaning of "neoplastic disease" as "cancer," essentially using the terms interchangeably, an idea that is also supported by the prosecution history. (D.I. 89 at 56-58). Defendant responds that while "neoplastic diseases" generally refers to all cancers, the patent narrowly focuses on "solid" cancers because all the examples of cancers in the patent are solid tumor cancers. (D.I. 89 at 59).

Both parties agree that neoplastic diseases generally refers to cancer, solid or not.

Plaintiff has the better argument here because Defendant is narrowly construing the term by limiting it to the preferred embodiments. While Defendant is correct to note that the specification states that "[t]he instant invention is more particularly directed to a method for the treatment of solid neoplasms," Defendant ignores the previous sentence that states "the present invention is directed to a method for the treatment of neoplastic diseases in a mammal..." ('346 Patent, 9:61-67). That the specification sometimes modifies neoplasms with "solid" demonstrates that neoplasms, when used in the patent without the "solid" modifier, must be more than just solid cancers. If the claim used "solid neoplastic diseases," Defendant's argument would win, but the claim does not. Neoplastic diseases means cancers.

- 5. "said neoplastic diseases are sensitive to said enhanced combination"
- a. Plaintiff's proposed construction: said neoplastic diseases are sensitive to said synergistic combination

- b. Defendant's proposed construction: indefinite
- c. Court's construction: indefinite

For the reasons offered in the analysis of the above terms, this term is also found to be indefinite.

III. CONCLUSION

Within five days the parties shall submit a status report.